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VIA ECF & FEDEX

The Honorable Michael A. Hammer, U.S.M.J.
United States District Court
Martin Luther King, Jr. Federal Building
50 Walnut Street, Room 2060
Newark, New Jersey 07102

HIGHLY CONFIDENTIAL

Re: *Celgene Corporation, et al. v. Hetero Labs Limited, et al.*
Civil Action No. 17-3387 (ES)(MAH)

Celgene Corporation, et al. v. Par Pharmaceutical, Inc., et al.
Civil Action No. 17-3159 (ES)(MAH)

Dear Judge Hammer:

This firm, together with Quinn Emanuel and Jones Day, represents plaintiff Celgene Corporation (“Celgene”) in the above-captioned matters. Celgene submits this letter in opposition to Defendants’ request to amend their non-infringement contentions for U.S. Patent No. 8,828,427 (the “427 patent”). *See* No. 17-3387 at D.I. 216; No. 17-3159 at D.I. 103.¹

As Defendants stated in a November 6, 2017 letter to the Court—*at the outset of this case*—“Defendants believe[d] it [was] clear from their respective ANDAs that . . . Plaintiff[s] [would] thus assert . . . infringe[ment] under the doctrine of equivalents.” D.I. 60 at 5 n.2. As such, Defendants requested that Magistrate Judge Dickson include a date in the case schedule by which Defendants could “freely amend” their contentions in response to Celgene’s contentions without leave of court. *Id.* at 1. Judge Dickson denied Defendants’ request, holding that L. Pat. R. 3.7 would govern any proposed amendments. *See* D.I. 67 at 3. Judge Dickson explained:

If, after preparing their contentions *using all of the information available to them at the time*, Defendants are still so legitimately blindsided by Plaintiffs['] contentions that they must change their own, Defendants will likely have a strong “good cause” argument for amendment pursuant to Local Patent Rule 3.7. If, however, they seek amendment to *add information previously available to them*, then their proposed amendment would likely be *improper*.

¹ All “D.I.” cites herein are to No. 17-3159 unless otherwise stated.

Id. (emphasis added).

As explained below, the objected-to portions of each Defendant's proposed amendments are improper because they seek to add information previously available to Defendants.² This is evidenced by the fact that the individual Defendants seek to now add information that is found: (1) in Defendants' own ANDAs and the '427 patent's publicly-available file history—both of which were available to Defendants before this case began; (2) in Defendants' Joint Invalidity Contentions that were served contemporaneously with each Defendant's original non-infringement contentions; and/or (3) in other Defendants' original non-infringement contentions. Thus, Defendants cannot demonstrate the "good cause" necessary under L. Pat. R. 3.7 to add new theories to the case. The objected-to portions of the amended contentions should not be permitted for this reason alone.

Defendants' primary argument with respect to good cause is that Celgene's contentions contain an argument about the "ratio" of excipients that Defendants could not have anticipated. D.I. 103 at 5 ("Defendants were surprised by Celgene's 'ratio' argument.") In fact, Defendants' refer to the "ratio" argument more than 20 times in their letter request. But this is a red herring. Celgene *consented* to Defendants' amendments responding to Celgene's "ratio" argument. *See* D.I. 97 at 2 (Defendants' motion to amend on consent). Accordingly, any purported surprise based on Celgene's arguments concerning the ratio of excipients cannot support a finding of good cause for the objected-to portions of Defendants' proposed amended contentions.

Because Defendants cannot show good cause, it is not necessary to analyze prejudice under the Local Patent Rules and this Court's precedent. That prejudice, however, further supports denying Defendants' application. Despite Defendants' May 23, 2018 notification of their intention to amend, Defendants did not file their request until September 6, 2018, first delaying more than a month before providing proposed amendments for Celgene's consideration, and then more than another month after the parties reached an impasse. As explained below, the parties completed significant work during that time, including solidifying claim-construction positions based on Defendants' original contentions.

While Defendants now claim that "this case is still in its early stages" and that the schedule can be modified, Defendants previously told Your Honor—in arguing for an expedited schedule—that the parties engaged in "very considerable fact discovery" and that "the only thing we have left to do is take fact dep[osition]s." (Ex. 1, 5/11/18 Tr. at 9-10.) If Defendants' request is granted, the case schedule will need to be extended significantly to give Celgene adequate time to work with its experts, prepare amended infringement contentions, serve new fact discovery requests, and prepare new claim construction positions. In other words, significant portions of the work the parties have done to date will need to be *redone*, and the case schedule will be significantly disrupted as a result. This is further reason to deny Defendants' request.

² With the exception of Mylan's proposed amendments—to which Celgene objects in full—Celgene objects only to certain portions of each Defendant's amended contentions. For Teva, Apotex, Hetero, and Aurobindo, those objections are shown in the highlighted portions of the proposed amendments. For Breckenridge, the objections are shown in the struck-through portions of the proposed amendments. Mylan's proposed amendments are attached as Ex. 1 to D.I. 103. The other Defendants' proposed amendments are attached as Exs. A-E to D.I. 97.

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I. Background

Defendants served their original non-infringement contentions on December 15, 2017. Celgene served its infringement contentions on April 20, 2018. On May 23, 2018, Defendants asked Celgene to consent to Defendants amending their non-infringement contentions. (Ex. 2, 5/23/18 email from K. Reichenbach to F. Calvosa.) Defendants did not share their proposed amendments at that time. Instead, Defendants did not provide all of their proposed amendments until June 29, 2018 (Ex. 3, 6/29/18 email from J. Schramm to F. Calvosa), with the earliest proposed amendments provided by Breckenridge only on June 19, 2018 (Ex. 4, 6/19/18 email from K. Musgrove to F. Calvosa).

Celgene diligently analyzed all six Defendants' individual amendments and, by July 9, 2018, identified the proposed amendments to which it consented and those to which it objected. (*See, e.g.*, Ex. 5, 7/9/18 email from F. Calvosa to J. Schramm.) The parties then met-and-conferred, with the last of those conferences taking place on July 25, 2018. Despite that the parties were at an impasse as of July 25—with certain Defendants declaring an impasse even earlier (*see, e.g.*, Ex. 6, 7/23/18 email from N. Scharn to F. Calvosa)—Defendants waited at least an additional **43 days** to file their request for leave to add the objected-to portions of their proposed amendments. Defendants have provided no reason for this delay.

During that time, the parties completed all claim construction exchanges under the Local Patent Rules, met and conferred three times to narrow and focus their claim construction disputes, and submitted a Joint Claim Construction and Prehearing Statement to the Court on August 29, 2018, solidifying their claim construction positions based on the original contentions. *See* D.I. 100. And since Defendants served their original non-infringement contentions in December 2017, Celgene has undertaken significant work to review Defendants' ANDAs and develop infringement theories, develop those theories into infringement contentions, prepare discovery requests seeking information to support those contentions, and commit to claim construction positions. Defendants now ask Celgene to redo a significant amount of that work.

II. Argument

A. Disclosure Requirements of the Local Patent Rules

The Local Patent Rules are “designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed Distinguishable from the liberal standard for amending pleadings, the philosophy behind amending claim charts is decidedly conservative” *King Pharms., Inc. v. Sandoz, Inc.*, No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010) (citations and quotations omitted), *aff'd* 2010 WL 4789950 (D.N.J. Sept. 8, 2010) (Brown, C.J.). “Particularly, in the District of New Jersey, the Local Patent Rules emphasize ‘*ultra* early disclosure of infringement and invalidity contentions for patent cases arising under the Hatch-Waxman Act.’” *Jazz Pharms., Inc. v. Roxane Labs., Inc.*, No. 10-6108, 2012 WL 3133943, at *3 (D.N.J. July 30, 2012) (quoting *Sanofi-Aventis v. Barr Labs., Inc.*, 598 F. Supp. 2d 632, 637 (D.N.J. 2009)), *aff'd*, 2013 WL 785067 (D.N.J. Feb. 28, 2013) (Salas, J.). Under L. Pat. R. 3.7, amendments to contentions “may be made only by order of the Court upon a timely application and showing of good cause.” (emphasis in original).

B. Defendants Cannot Show Good Cause for Their Proposed Amendments

Defendants' request focuses heavily on Celgene's infringement contentions under the doctrine of equivalents as a reason to permit amendment. As explained above, however, Judge Dickson already rejected Defendants' position that such contentions would justify an amendment as of right. Under Judge Dickson's ruling, Defendants' proposed amendments are "improper" because the new contentions that Defendants seek to add are based on information known to Defendants *prior* to service of their original non-infringement contentions. *See* D.I. 67 at 3-4. Celgene's reliance on the doctrine of equivalents in its infringement contentions does not automatically create "good cause" for Defendants to amend their contentions.

Moreover, Defendants misleadingly rely on arguments that do not apply to the objected-to amendments that Defendants seek to introduce. For example, Defendants cite the "ratio" arguments in Celgene's infringement contentions as an alleged basis to permit the disputed amendments.³ *See, e.g.*, D.I. 103 at 4-5. But Celgene *consented* to the proposed amendments of Apotex, Hetero, Breckenridge, Aurobindo, and Teva that constitute responses to such arguments. The disputed amendments, on the other hand, do not respond to Celgene's "ratio" arguments under the doctrine of equivalents. Thus, any purported surprise from Celgene's "ratio" arguments cannot provide good cause for the disputed amendments.

Rather, as explained below, the disputed amendments focus on arguments that Defendants could have, and should have, included in their original non-infringement contentions. To be clear, Defendants did not serve joint non-infringement contentions—they, of course, each served their own non-infringement contentions specific to only their respective ANDAs. Tellingly, however, rather than focusing on the specific amendments that each individual Defendant proposes, Defendants present their arguments as a whole in an effort to cover up the glaring deficiencies and inconsistencies in their respective proposed amendments. Celgene addresses each Defendant's individual amendments in turn:

1. Teva

[REDACTED]

[REDACTED]

³ Celgene disagrees with Defendants' allegation regarding the use of the term "ratio" (*see* D.I. 103 at 5), but the actual merits of Celgene's infringement contentions are irrelevant to the issue of whether Defendants should be granted leave to amend their contentions.

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[REDACTED]

[REDACTED]

[REDACTED]

2. Aurobindo

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

3. Breckenridge

[REDACTED]

[REDACTED]

[REDACTED]

4. Hetero

[REDACTED]

[REDACTED]

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5. Apotex

[REDACTED]

[REDACTED]

[REDACTED]

6. Mylan

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

C. Celgene Would Be Prejudiced By Defendants' Proposed Amendments

As explained above, Defendants cannot demonstrate good cause to permit the objected-to amendments. Thus, the Court need not consider the prejudice to Celgene to deny Defendants' requested relief. *Jazz Pharms.*, 2013 WL 785067, at *5 ("Only if the [party seeking to amend its contentions] is able to show diligence may the court consider the prejudice").

Even if prejudice is considered, however, the prejudice to Celgene provides another basis to deny Defendants' attempted amendments. Specifically, Celgene would be unfairly prejudiced if Defendants are permitted to add their new non-infringement theories at this time, and the case schedule would be severely disrupted as a result. As noted above, the parties completed all claim construction exchanges under the Local Patent Rules and submitted a Joint Claim Construction and Prehearing Statement to the Court on August 29, 2018, solidifying their claim construction positions based on the original contentions. *See* D.I. 100. Furthermore, since Defendants served their original non-infringement contentions in December 2017, Celgene has undertaken significant work to review Defendants' ANDAs and develop infringement theories, prepare those theories into infringement contentions, prepare discovery requests seeking information to support those contentions, and commit to claim construction positions.

Allowing Defendants' proposed amendments would require Celgene to redo a significant amount of that work. For example, Celgene and its experts would be required to go back and redo the investigation into Defendants' ANDAs. Celgene would also be required to reconsider its claim construction positions and very likely would propose at least one new term from the

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'427 patent for construction. Celgene has not undertaken such investigations to date because there is no good cause for Defendants' proposed amendments and Celgene submits that it should not be required to undertake the expense of such efforts in the absence of good cause. Further, if Defendants' amendments are allowed, Celgene submits that the case schedule would require significant extensions (at least five to six months), including: (1) at least an additional 45 days, as provided for under the Local Patent Rules, for Celgene to investigate and amend its infringement contentions; (2) at least an additional two months thereafter for Celgene to serve and receive responses to new discovery requests directed to Defendants' amended contentions, but likely longer given Defendants' already deficient discovery responses to date; and (3) at least an additional two-and-a-half months thereafter, under the time contemplated by the Local Patent Rules, for the parties to redo the claim construction exchanges and discovery before filing opening *Markman* briefs.

Defendants' claim that Celgene is not prejudiced, because Defendants were allegedly diligent in seeking to amend (D.I. 103 at 9), lacks merit. The Local Patent Rules require that a party must prove not only that it was diligent in moving to amend, "but also that it was diligent in its search for [information relevant to its contentions]." *Jazz Pharms*, 2013 WL 785067, at *3. Here, Defendants cannot prove either. As stated above, Defendants inexplicably injected multiple delays into their efforts to amend their non-infringement contentions. *See supra* at p. 3. Furthermore, the objected-to portions of Defendants' proposed amendments are all based on information that was available to Defendants long before their original non-infringement contentions were served. Thus, Defendants were not diligent and the prejudice to Celgene is significant. Although the Court need not consider prejudice, the prejudice to Celgene only further supports denial of Defendants' request.

III. Conclusion

For the foregoing reasons, Celgene respectfully requests that the Court deny Defendants' request for leave to amend their non-infringement contentions.

Thank you for Your Honor's kind attention to this matter.

Respectfully yours,



Charles M. Lizza

Exhibits

cc: Counsel of Record (via e-mail)